## **DEPARTMENT OF THE ARMY SUPPLY BULLETIN**

## **Army Medical Department Supply Information**

Headquarters, Department of the Army, Washington, DC 20310-2300

20 March 2007

Effective until rescinded or superseded

#### DISTRIBUTION STATEMENT A: Approval for public release; distribution is unlimited

Printing of this information does not constitute endorsement of the product, manufacturer, or the use of any related item thereof by the U. S. Army.

#### REPORTING ERRORS AND RECOMMENDING IMPROVEMENTS

You can improve this publication. If you find any mistakes, or you know a way to improve it, please let us know. Mail your letter or DA Form 2028 (Recommended Changes to Publications and Blank Forms) directly to the U.S. Army Medical Materiel Agency, ATTN: MCMR-MMA, Fort Detrick, MD 21702-5001. If you prefer using email, please address it to usammacrm@amedd.army.mil.

	<u>Table of Contents</u>	<u>Page</u>
	- Vaccines and Temperature-Sensitive Medical Products	
Appendix A	- Sample Form of Medical/Dental Product Quality Deficiency Report (M/DPQDR)	A-1
•		
Index		IN-1

#### SPECIAL NOTICE

THIS SUPPLY BULLETIN IS DEDICATED ENTIRELY TO

MEDICAL MATERIEL INSTRUCTIONS FROM THE

US ARMY MEDICAL MATERIEL AGENCY FOR THE DEPARTMENT OF DEFENSE

## Errata Sheet For SB 8-75-SB-S1 dated 20 January 2007

The Chapter following this page should have been included in the *SB 8-75-S1*, dated 20 January 2007. Subsequent editions of the *SB-S1* will include any updates, revisions, or deletions to the **MEDCOM Guide to TDA Changes/Equipment Authorizations TDA requirements for the US Army**.

The USAMMA apologies for any inconvenience by the omission of this Appendix and appreciate your understanding.

POC for any additional information or any questions concerning the Appendix is:

MEDCOM HEADQUARTERS ATTN: USAMEDCOM - MCLO-O 2050 Worth Drive Fort Sam Houston, TX DSN 471-7246 or Comm 210-221-7246

#### **CHAPTER 5. MEDCOM GUIDE TO TDA CHANGES**

- a. The attached *MEDCOM Guide to TDA Changes/Equipment Authorizations* is for guidance use only. It is not an AR, DA-PAM, or other required publication with set rules. It is, however, a complete and authoritative MEDCOM guide to follow until a final copy is approved.
- b. Any questions or comments regarding this *Guide* should be directed to the USAMMA point of contact:

US Army Medical Command Headquarters ATTN: USAMEDCOM - MCLO-O 2050 Worth Drive Fort Sam Houston, TX DSN 471-7246 or Comm 210-221-7246

#### **MEDCOM Guide to TDA Changes/Equipment Authorizations**

**Summary.** This pamphlet provides guidance and instructions for preparing and submitting requests for changes to TDA for equipment listed in Section III.

**Applicability.** This pamphlet applies to all activities assigned to US Army Medical Command (MEDCOM).

## Chapter 1 General

**1.1 Purpose**. The purpose of this pamphlet is to define MEDCOM's role in documentation and set procedures and guidance for preparing and submitting TDA change requests. This pamphlet clarifies guidance from various Army regulations and is intended as a ready reference for use by MEDCOM activities at all levels of command. When a conflict exists between guidance contained in this pamphlet and a Headquarters, Department of Army (HQDA) publication, HQDA policy will be followed. Most MEDCOM medical equipment is authorized by AR 40-61. However, Department of Army (DA) controlled items of medical equipment as identified by SB 700-20 require TDA documentation. Guidance is available in AR 71-32.

## Chapter 2 Tables of Distribution and Allowances (TDA)

#### 2.1 Proponent

The United States Army Force Management Support Agency is the HQDA proponent agent for TDAs. Approval authority for DA controlled TDA equipment is DA, G-3. "DA Controlled" items can be identified by researching the CIC code in SB 700-20. Most items of equipment are found in Chapters 2 and 6. Chapter 4 has been reserved for new or experimental items. If the CIC contains the letter "C", the item is a DA controlled item and must be approved by DA, G-3 and USAFMSA prior to being purchased. If the CIC code lists an "O", the item is approvable at MEDCOM level. Only equipment items with Line Item Numbers (LIN) assigned can be added to the TDA. Chapter 8 of SB 700-20 contains a listing of CTA items. CTA items cannot be added to the TDA. The CTA, itself, is the authorization for you to have the item of equipment. The G-3/FMP TDA Equipment Review and Validation Board will approve or disapprove all TDA equipment requests for all intensely managed items contained in Supply Bulletin 700-20. Chapters 2 and 4, that are coded as Controlled Item Code (CIC) "C" and Reportable Item Control Code (RICC) "2" or equivalent. HQDA controlled items of equipment may only be requisitioned or issued to an organization when it is included in an approved authorization document. For MEDCOM units, this means the item must be approved and listed in the Section III portion of the activity's TDA prior to purchasing. Adherence to this policy will be an item of command interest in future Command Logistics Review Team (CLRT) visits.

The MEDCOM retains the authority to document all equipment transfers between paragraphs inside a specific Unit Identification Codes (UICs). Requests to document transfers of LINs between UICs within the same MACOM will be forwarded to the Equipment Review and Validation Board for decision only if the LINs are intensively managed as noted above. All requests to document Inter-Command equipment transfers must be submitted through G-3/7/FMP to the TDA Unit Equipment Review and Validation Board for review and decision and include concurrence signed by an officer (COL, GS-15 or above) in the losing command. The Equipment Review and Validation Board will convene no earlier than the 16<sup>th</sup> day of each month.

Board decisions will be distributed no later than the last working day of each month. After the Board approves the DA Form 4610-R, G-3/7/FMP will approve a documentation strategy. If the LIN is critical to the unit or activity then an Out of Cycle (OOC) document will be directed for implementation. The HQ, MEDCOM is the approval authority for those DA controlled items coded "MAPP" (MACOM approval) in SB 700-20, those included in the Force Management Bulletin Board for which requirements have been established in Basis of Issue Plans (BOIPs) and approved by HQDA and those select DA controlled items of equipment for Training Support Centers for which USAFMSA granted a waiver.

BOIPs are developed for new or improved items of equipment. A BOIP describes in detail a new item, its capabilities, component items of equipment, where the item is to be used, and identifies the associated support items of equipment and personnel. BOIPs are required documents used to plan and manage the introduction of developmental and non-developmental items of equipment. It is not an authorization document. It is a requirements document!

The MEDCOM retains the authority to document all equipment deletions.

#### 2.2 How TDAs are Organized

- a. TDA Development. The TDA prescribes the organizational structure for a unit having a support mission for which a Table of Organization and Equipment (TOE) does not exist and may include civilian positions. They are developed based on the type and level of workloads associated with the unit's mission.
  - b. TDA Composition. The TDA document is composed of three sections as follows:
- (1) Section I, General. Includes unit designation, mission statement, capabilities, and administrative data.
- (2) Section II, Personnel Allowances. Contains by paragraph and line number, detailed information on required and authorized personnel, followed by a recapitulation by civilian and/or military grade and skill and Army Management Structure Code (AMSCs), of all positions in the organization.
- (3) Section III, Equipment Allowance. Contains by paragraph and LIN, all equipment required and authorized for the unit, followed by a recapitulation in LIN sequence.

#### 2.3 Responsibilities

Installation/Activity Commanders will:

- a. Ensure that <u>no</u> DA controlled items of equipment are purchased prior to receiving approval from the DA, G-3.
- b. Report unused equipment as excess and delete from authorization documents unless justified for retention by a letter request or an economic analysis or as job peculiar.
- c. Institute procedures to ensure turn-in or transfer of excess equipment identified by equipment authorization surveys within timeframe identified.
- d. Designate one person within logistics as the Equipment Manager. This would normally be the Property Book Officer (PBO).
  - e. Approve all DA 4610-Rs by signing and submitting a transmittal letter to MEDCOM.

#### 2.4 Equipment Usage Management

In the area of equipment usage management, the Army's objective is to obtain optimum use and efficient management of equipment used by TDA activities to meet mission requirements with the minimum of equipment. Usage of medical equipment will be managed per AR 40-61.

#### 2.5 Guidelines for Changing Authorization Document

Most changes originate at the unit level with the need or desire for changes (more, less or different equipment). There are several ways to achieve the desired change (cross level, hand receipt, local purchase, contracting etc.) but changing an authorization document is probably the slowest.

- a. How to Submit a Change. Use the following steps to submit an authorization document change:
  - (1) Determine the change needed.
- (2) Consult the current and future versions of the TDA to see if the change has already been applied. Note: The activities' Resource Management Division has copies of the latest TDA and change documents.
- (3) Prepare the request for change utilizing guidance in this document, DA Form 4610-R, *Equipment Changes in MTOE/TDA*, and AR 71-32.
- (4) Make sure the justification is clear and can be understood by someone not familiar with your unit organization or method of operations. MEDCOM unit structure is very diversified; no two or alike. The clearer and more logical the justification, the better the chance it will be approved. Requests for equipment changes must be approved by the Equipment Review and Validation Board managed by DA, G-3.
  - (5) Ensure all numbers add up.

#### 2.6 Procedures For Changing TDA Equipment

An activity submits a completed DA Form 4610-R, *Equipment Changes in MTOE/TDA*, to USAMEDCOM, ATTN: MCLO, with a copy furnished to the activity's Resource Management (RM) office. It is critical to keep the Resource Management office informed! A cover memorandum will be prepared and signed by the activity commander, (COL, GS-15 or above). MEDCOM will ensure that all requirements of AR 71-32 have been met and will forward the packet to DA, G-3 for presentation to the G-3 Equipment Review and Validation Board. If approved at G-3, the packet will then be submitted to USAFMSA for documentation in the next Management of Change (MOC) window. The MOC window usually opens in January of each year. If the packet is disapproved it will be sent back through the chain of command for rework or more justification. The importance of the justification cannot be overstated. Justifications should be very thorough and explain why the item is needed. One line justifications are no longer adequate for presentation to the board. AR 71-32, Appendix E provides a comprehensive checklist to follow in writing justifications. The following are important areas that need to be addressed in each justification:

- a. Show that the request has been reviewed by interested staff agencies (As applicable).
- b. Include a statement in the justification on why like items presently authorized cannot be used to accomplish the mission.
  - c. State the function the item will serve and how it will be used.
  - d. State the specific impact on unit mission if the item is not obtained.
- e. When the request is for support of a new mission, cite the authority to perform the mission and clearly state how the requirement(s) will be satisfied.
- f. When tactical communications equipment is being requested for a TDA unit comply with paragraph D-57 and paragraph N-4, AR 71-32.
- g. When the request is based on an increase in equipment usage, consider actual use of all like type equipment on the current TDA considered to determine whether the increase can be accommodated within current resources. State why it is not feasible.

- h. Include the DA TMDE registration number (DA Pam 700-20) with request for TMDE. TMDE should never be procured prior to receiving approval from the MEDCOM TMDE Coordinator.
- i. When commercial equipment (SB 700-20, Chapter 6) is being requested, consider standard items that are excess to total requirements.
- j. When the request pertains to tool sets, test equipment, and other maintenance related items, cite the level of maintenance to be performed, the end item to be maintained and the page numbers of the technical manual ™ that prescribes the specific use.
- k. When the request pertains to power driven equipment, include a statement as to the source of power for such equipment.
- I. When the request is for Materials Handling Equipment (MHE) provide evidence of coordination with the appropriate installation MHE control office.

#### 2.7 Before Preparing TDA Equipment Changes

- a Contact your Resource Management office to ensure you are reviewing current authorization in the latest approved/projected TDA.
- b. If nothing suitable is presently authorized, review SB 700-20 to determine additional requirements.
  - c. Determine what items, if any, can be deleted if requested equipment is approved.
  - d. Ensure current manpower authorizations are sufficient to support additional equipment.
- e. Ensure that equipment requested is the minimum essential for mission accomplishment; not just "nice to have".
  - f. Ensure the requirement cannot be met by borrowing from another activity.
- g. Ensure that mixing of models of the same type of equipment is kept to a minimum or eliminated.
- h. Ensure that requested equipment can be maintained with currently authorized maintenance personnel and equipment.
  - i. Ensure that facility size and structure can accommodate the new equipment.
  - j. Ensure that requested equipment is compatible with already authorized equipment.
- k. Ensure that equipment is not already authorized by a Common Table of Allowances (CTA).

#### 2.8 Preparing TDA Equipment Change Requests

A TDA Equipment Change Request Package will consist of a Memorandum of Transmittal, complete and properly prepared DA Forms 4610-R, and any supporting documentation required.

- (1) Memorandum of Transmittal. Prepare a Memorandum of Transmittal for "DA Controlled" equipment which requires DA, G-3 approval. The memorandum should be signed by a Colonel or GS-15 or higher. Each Memorandum will contain only DA Forms 4610-R for no more than one UIC. Subject of transmittal memorandum should indicate "DA Controlled", e.g., Request for DA Controlled Equipment. Each cover memorandum for approval will contain the following standard paragraph: "The equipment requested on the form(s) and the justifications(s) provided have been reviewed by this command, and the equipment requested has been validated to be the minimum essential for mission accomplishment. Where applicable, equipment has been identified for deletion, if this request is approved."
- (2) DA Forms 4610-R (Figures 2-1 and 2-2). Submit a complete DA Form 4610-R. See AR 71-32, Chapter 6 for additional guidance and to ensure proper completion.
- (3) Tactical Wheeled Vehicles (TWV): The Tactical Wheeled Vehicle Requirements Management Office (TWVRMO) is tasked by HQDA to review current initial issue quantities; Table of Organization & Equipment (TOE), Modified Table Of Organization & Equipment (MTOE), Table of Distribution and Allowance (TDA), and the Basis of Issue Plan (BOIP) documentation; and associated justification to provide impact analysis and maintain an audit trail of the fluctuations to the overall Tactical Wheeled Vehicle (TWV) fleet. DA Form 4610-R and the TWVRMO Questionnaire for TWV will be forwarded through command channels. Per AR 71-32, Chapter 6, all requests for tactical wheeled vehicles will be reviewed by the Tactical Wheeled Vehicle Requirements Management Office (TWVRMO), Fort Eustis, VA. To avoid unnecessary

delays TWV requirements should not be mixed with other HQDA controlled equipment on the same request. TWV request packets should be sent through MEDCOM and not directly to the TWVRMO. MEDCOM will review and forward the request.

- (4) Non-tactical Vehicles (NTVs): If an organization has their own account with GSA and does not utilize the installation transportation motor pool (TMP) for support, these vehicles must be authorized on the activity's TDA. If, however, the activity is drawing vehicles from the installation and reimbursing, then these vehicles would be documented in the installation TDA, not the MEDCOM activity's TDA.
- (5) Government Owned/Contractor Operated (GOCO) Equipment. Submission of DA Forms 4610-R is not required for GOCO equipment. Any contract that obligates the government to provide equipment to a contractor is recognized as an authorization document for purposes of requisitioning. The Contracting Officer for the respective Commands will be the approving authority for this equipment.
- (6) Commercial Non-standard Equipment: Submission of DA Form 4840-R requesting LIN assignment is required for commercial nonstandard equipment with a unit cost of \$250,000 or over. A package consists of a Memorandum of Transmittal, properly completed DA Form 4840, Request for Type Classification Exemption (TCE)/LIN for Commercial Equipment, and manufacturer's brochure, photographs, drawings or specifications. These items can then be documented in the TDA once the LIN is assigned and appears in SB 700-20. With the exception of those class items listed in AR 71-32, Chapter 6, commercial nonstandard equipment with a unit cost of less than \$250,000 is subject to local approval. TCEs are normally not required on systems unique to the Army Medical Department such as nurse call systems etc, These should be handled on a case by case basis.

#### 2.9 Equipment not to be Documented in TDAs

- a. Equipment authorized in another document and used for the same purpose.
- b. Equipment authorized by another TDA.
- c. Equipment on hand through temporary loan.
- d. RDTE equipment purchased with RDTE funds.
- e. Maintenance float, sizing float, repair parts and expendable or durable items.
- f. Equipment procured with non-appropriated funds.
- g. Prefabricated buildings.
- h. Operational float stocks obtained under AR 710-1.
- i. Real property.
- k. Equipment procured exclusively for DoD civil defense efforts.
- I. Any nonexpendable item of serviceable equipment that is withdrawn from the Defense Reutilization and Marketing Office (DRMO).
  - m. Equipment used for experiments and tests.

## Chapter 3 Guidance for Selected Types of Equipment

#### 3-1. Ammunition and Related Items

- a. Targets, target equipment, and ammunition are authorized by CTA 50-909.
- b. Training ammunition authorizations are provided to MACOMs by DA training ammunition memorandum.

#### 3.2. Armament and Weapons

- a. General. Weapons included in TDAs will be limited to the minimum essential types and quantities.
- (1) Individual Type Weapons. These weapons are provided for the protection and security of the unit, personnel in the unit, or the wounded and sick in their charge. Weapons are not authorized for chaplain and general officers. As a rule, individual weapons on hand will not exceed the total number of required, authorized, or assigned personnel. General officers are authorized a weapon per AR 725-1.
  - b. TDA Activities.
- (1) Each military individual assigned to OCONUS TDA organizations and to CONUS based TDA organizations with contingency missions to support deployed forces requiring movement of personnel into threat areas will be provided an individual weapon in accordance with the appropriate basis of issue (BOI). The exception is AMEDD personnel assigned to TDA activities in OCONUS commands who will be authorized individual weapons on the basis of one-for-two individuals. Alaska and Hawaii and other areas outside the contiguous United States are included in geographical connotation of OCONUS.
- (2) Ceremonial Rifles. Selected honor guards established per AR 71-32 will use the M14 as the honor guard rifle. Other honor guards not recognized by this regulation but have been approved by MACOM commanders will also use the M14. Honor guards other than described above, color guards, and burial details will be equipped with presently authorized TDA weapons.
- (3) Bayonets. Bayonets are authorized for all individuals authorized an individual weapon except medical personnel and medical units, Chaplains are not authorized bayonets, but chaplain's assistants are, since they are issued individual weapons.

#### 3-3 Books

Those nonexpendable books or publications required by TDA units will be included in section III of the TDA if listed in SB 700-20 and <u>not</u> carried on library accounts. Book sets are listed as sets in SB 700-20.

#### 3-4 Camouflage Clothing and Equipment

- a. CTA 50-900 authorizes individual camouflage clothing and equipment.
- b. Requirements and authorizations for camouflage net requirements will be included in the TDA.
- c. Camouflage net requirements for the purpose of supporting specific operations, contingencies, or war plans for a specific geographic area should be justified as operational project items under AR 710-1.

#### 3-5. Chaplain and Chapel Equipment

CTA 50-909 authorizes chaplain and chapel equipment.

#### 3-6. Civilian Guard Equipment

CTA 50-900 authorizes civilian guard equipment.

#### 3-7 Clothing and Individual Equipment (CIE)

- a. Prescribed Items. The following publications are the only DA authorization documents permitting the use of appropriated funds to procure individual and organizational CIE for personnel in the Army.
- (1) AR 700-84. Authorizes civilian clothing for military individuals, special measurement clothing and clothing for prisoners in Army installation confinement facilities.
  - (2) CTA 50-900. Authorizes individual clothing and equipment
  - (3) CTA 8-100. This authorizes AMEDD expendable/durable items.
- (4) CTA 50-970. This authorizes expendable/durable items (except medical, class V, repair parts, and heraldic).

#### 3-8 COMSEC Equipment

COMSEC equipment to provide secure transmission of information will be documented as required if meeting requirements outlined above and in SB 700-20. Note: The old STU III phones are CTA items. The new tactical STE phone is a TDA item.

#### 3-9 Dayroom Furniture

CTA 50-909, Tables 41, 42, and 43 authorizes dayroom furniture.

#### 3-10 Flags and related Items

- a. Heraldic items. Heraldic items are described in AR 840-10 for display by organizations and individuals such as guidons, flags etc. They will not be included in the TDA.
- b. Nonheraldic items. CTA 50-909 and 50-970 authorize nonheraldic flags and related items.

#### 3-11 Food Service Equipment

CTA 50-909 authorizes equipment with unit cost less than \$250,000 for all Army appropriated fund food service facilities. Army appropriated fund food service equipment costing \$250,000 and over is authorized by the TDA.

#### 3-12 Laundry and Dry-cleaning Equipment

CTA 50-909 authorizes equipment with unit cost less than \$250,000. Fixed laundry and drycleaning equipment costing \$250,000 and over is authorized by TDA.

#### 3-13 Materials Handling Equipment (MHE)

For storage operations forklift requirements will be computed as prescribed in AR 71-32, Appendix D-29, Tables D-1, D-2, D-3 and D-4..

#### 3-14 Protective Masks

Protective masks are documented in the TDA as follows:

- (1) Each individual (military and civilian) in an OCONUS TDA organization operating in a chemical or biological threat area will be authorized a protective mask of a type commensurate with the individual duty position.
- (a) The basis of issue for a civilian in an OCONUS TDA organization is one per emergency essential civilian designated on the OCONUS mobilization TDA and one per civilian designated as host nation support and not otherwise provided a protective mask.

- (b) Protective masks are not authorized for family members or other civilians not listed above.
- (2) Individuals assigned to CONUS-based TDA organizations with missions to support deployed forces requiring injection of personnel into chemical or biological threat areas will be authorized a protective mask commensurate with the individual's duty position. This also applies to civilian employees who have agreed to deploy with an organization.
- (3) CONUS-based non-deployable organizations will include sufficient masks in TDA to meet unique mission requirements or to support individual proficiency.
- (4) Units may stock up to 105 percent of the TDA authorization to enhance readiness by facilitating ready exchange or replacement items which are defective or of incorrect size.

#### 3-15 Recreation Equipment

CTA 50-909 authorizes recreation equipment for physical training programs. Recreation equipment costing greater than \$250,000 will be placed on the TDA.

#### 3-16 Relocatable Buildings

Relocatable buildings will normally be accounted for as real property and not be included in the TDA.

#### 3-17 Tentage, Tarpaulins, and Related Items

CTA 50-909, Table 61 authorizes tentage, tarpaulins, and related items costing less than \$250,000. Items cost greater than \$250,000 will be place on the TDA.

#### 3-18 Tool Sets

Tool sets and equipment for machinists, mechanics, repairers, helpers, and similar categories of personnel will be provided to military and civilian personnel on an individual basis in TDAs as required. Consideration will be given to quantities of available equipment, number of shifts in operations and minimum allowances required to accomplish the mission. Standard items should be procured as much as possible.

#### 3-19 Training Devices

Training devices are authorized on the training support center TDA, unless another TDA or TDA paragraph has been authorized as an exception per AR 25-1. In turn, the devices will be issued on a loan basis to using activities as required.

#### 3-20 Aircrafts

Aircraft will be authorized for inclusion in TDA units only when a continuing need is demonstrated. Justification will show, by reference to the appropriate TDA, that sufficient supporting personnel and equipment are authorized, or will be authorized to operate and maintain the requested aircraft. Appendix D, Section II Aircraft, AR 71-32 details requirements of procuring and documenting aircraft.

#### 3-21 Communication Equipment

In TDA activities, communications equipment requirements and allowances will be determined in accordance with policy and procedures in AR 25-1. Authorizations will only be approved when justified as a continuous requirement vital to the mission of the unit.

#### 3-22 Motor Vehicles

- a. Vehicles will be included in TDA in the minimum justified and approved quantities required to provide essential mobility to maintain the mission capabilities of units and activities.
- b. <u>Vehicles will not be authorized to individuals, but will be authorized on the basis of</u> functional or activity requirements.
- c. Vehicles will not be authorized for the sole purpose of transporting infrequently moved equipment. DA DCSLOG established a MACOM ceiling for all authorized non tactical vehicles (NTV). Each MACOM has a ceiling with authority to increase, decrease or substitute vehicles between subordinate elements as long as the changes do not exceed the ceiling. The MACOM NTV ceiling can not be increased without express written approval of the DA DCSLOG.
- e. The non-tactical wheeled vehicle fleet contains motor vehicles for general purposes and passenger transport purposes. These will be authorized by TDA. Per AR 71-32, motor vehicle requirements for this type of vehicle will be authorized in the transportation motor pool paragraph of the installation TDA. The only exception is that GSA lease general purpose and passenger transport vehicles may be documented in the Directorate of Public Works (DPW) paragraph of the installation TDA when the DPW has an existing lease for special purpose vehicles directly with GSA. Running motor pools is not in our core mission; vehicles should be drawn from the installation Transportation Motor Pool when possible. Authorization for prestige sedans are subject to Office of the Secretary of Defense (OSD) and Office of Management and Budget (OMB) approval. Additional information on both tactical and non tactical vehicles can be found in AR 71-32, Appendix D, Section IV.
- d. Requests for tactical vehicles must be approved by the Tactical Wheeled Vehicle Requirements Management Office (TWVRMO) prior to being submitted to the Equipment Review and Validation Office.
  - f. Materials Handling Equipment is not considered wheeled vehicles.

#### 3-23 Office Type Furniture and Equipment

Except as otherwise stated CTA 50-909 is the only DA authorization documents for office type furniture and equipment.

#### 3-24 Test, Measurement and Diagnostic Equipment (TMDE)

- a. Activities will comply with the acquisition requirements of AR 750-43, *Army Test, Measurement, and Diagnostic Equipment.*
- b. Route request through United States Medical Materiel Agency (USAMMA), 1423 Sultan Drive, Suite 10, ATTN: MCMR-MMM-B, Fort Detrick, MD 21702-5001 to the address listed in subparagraph c below.
- c. Receipt of acquisition approval from the U.S. Army TMDE Activity, ATTN: AMXTM-LM-A, Redstone Arsenal, AL 35898-5400, is necessary before requisitioning any item of TMDE. The acquisition request is now automated. You may request on-line using website <a href="https://TMDE-Register.us.army.mil">https://TMDE-Register.us.army.mil</a>. You will need an Army Knowledge Online (AKO) login and password to access the TMDE Register.
- d. The AR 750-43 lists those items exempt from acquisition approval. Preventive Medicine activities utilize many items of testing equipment that is exempt from the approval process, e.g., air flow meters, sound level meters etc.

#### 3-25 Research, Development, and Test Equipment (RDTE)

- (1) Equipment that will be documented includes:
- a. HQDA controlled equipment required for support of base operations at RDTE installations. This includes but is not limited to facility engineer, message center, security, motor pool, and installation maintenance.
- b. HQDA controlled equipment required for support of RDTE projects or specific test requirements for a period exceeding 2 years.
- c. Items acquired with RDTE funds for testing purposes which are still available at completion of the test program and are reassigned for operational use or inventory will be documented in the TDA.
  - (2) Equipment that will not be documented includes:
    - a. Equipment procured with RDTE funds.
    - b. Special purpose equipment required for RDTE activities.
    - c. Prototypes required by an RDTE activity to support experiments.

#### 3-26 Morale Support Activities

In order that the morale support activities program can meet the changing needs, interests, and off-duty requirements of the soldier and his or her family, equipment to support these programs are authorized as follows:

- (1) Investment (\$250,000 and over) equipment- installation TDA.
- (2) Expense (less than \$250,000) equipment- CTA 50-909.
- (3) Expendable or durable equipment- CTA 8-100 and CTA 50-970.

## Chapter 4 Command Review

Command involvement is of vital importance to ensure that only mission essential equipment is authorized. Review procedures will be established to ensure determination of the need before requesting an item. At the initiating level, the commander involved will explore all feasible alternatives prior to the submission of a material request. When, in the commander's opinion, the item desired is the most efficient and cost-effective to accomplish the mission, he or she will initiate the request

- a. When a request for a commercial item is being processed, the reviewing commander will compare the commercial item cost with that of the related standard adopted item, determine whether it is more cost effective to lease or purchase, and select an alternative, when possible, that will eliminate the need for the requested item of equipment.
- b. Commanders will review the need for all equipment during each annual inventory. Equipment no longer needed will be turned in, using normal supply procedures, and appropriate document changes will be initiated.
- c. Command control of equipment purchases with credit cards is essential to ensure that equipment is not purchased without following the above listed requirements. Controls will be put in place to prevent unauthorized purchases of equipment.

#### How to Prepare DA Form 4610-R for TDA Changes

#### I. Heading

- 1. Title of Functional Area. The using unit designation, which will be the TDA Paragraph Title (e.g. Equipment Maintenance, Provost Marshal etc.)
  - 2. UIC. Unit Identification Code (e.g., W2L6AA)
- 3. Unit Designation. The parent organization for which the basic TDA is established. (e.g., Womack Army Medical Center)
- 4. MTOE/TDA Number. The latest approved TDA (e.g., MCW2LAA). MC represents MEDCOM and should go before the UIC in this block.
- 5. CCNUM. Command Control Number of the Latest approved TDA (e.g., 0108). Changes can only be made against the latest approved TDA.
- II. Part I, Equipment, Section A Items to be Added and/or Deleted
- 6. Item Number. Each item being requested will be numbered in sequence (e.g., 1,2,3,4) for each paragraph of the TDA.
- 7. Paragraph. The TDA paragraph for which the equipment is being requested (user paragraph). The number listed must match the HQDA approved document being addressed. Ensure that you are using the latest FY 08 Hospital Template provided. The template was changed for FY 08 so paragraphs in older TDAs will not necessarily match. Resource Management should have a copy
- 8. LIN. The Line Item Number of the equipment being requested. LINs are found in SB 700-20. List the LINs in alphanumeric sequence for each paragraph (e.g., A56293, B04443, C19234). The items(s) requested must be the latest adopted one(s) per SB 700-20.
  - 9. ERC. Equipment Requirements Code. Indicate "C" for DA controlled items.
- 10. SB 700-20 Chapter. Indicate the chapter of SB 700-20 in which the LIN is located. Only items found in Chapters 2, 4, and 6 are placed on the TDA.
  - 11. Nomenclature. Use the item description as found in SB 700-20.
- 12. Cost. Use the unit cost found in the SB 700-20 (use cost of first one if more than one item is listed).
  - 13. Quantity Added, REQ/AUTH: Indicate the quantity you are requesting.
- 14. Quantity Deleted, REQ/AUTH: Indicate the quantity you wish to delete if it is associated with the simultaneous request for additional equipment. Be sure you are authorized the equipment you are trying to delete.
- 15. New Para Qty, REQ/AUTH: Indicate required quantity for LIN you are requesting plus any of the same LIN already authorized in the same TDA paragraph. If you are deleting an item, subtract the deleted quantity from the quantity already authorized in that paragraph.
- 16. New Recap Qty, REQ/AUTH: Check for the LIN in required/authorized columns of the "Recapitulation Section III Equipment" at the end of Section III Equipment of your TDA. Add the quantity in the recap, plus the quantity you are adding and indicate in this column. If you are deleting the item subtract the deleted quantity from the recap quantity.
- 17. Quantity on Hand, Not Auth: If any of the quantity you are requesting is already on hand, without TDA authorization, indicate in this column.
- III Part II Equipment, Section B. Items to be Deleted from Other MTOE/TDA

Use this section only when equipment being requested is to be transferred from another TDA in accordance with (IAW) instructions on the reverse side of DA Form 4610-R.

#### IV. Part III - Personnel

Use this section only to add or delete any position required to operate requested equipment. This section is usually non applicable and should be noted as N/A.

#### V. Part IV - Justification

Must be prepared IAW the checklist contained in Appendix E, AR 71-32. Follow these guidelines or your request will be returned. Each item will be numbered to correspond with item numbers on front of form. Justification will include why you need the equipment and how it will be used; NOT how the item(s) work(s). Also include what will happen if the request is not approved. Blanket justification for several items listed in Part II is not acceptable. Also include in the justification a Point of Contact (POC) and a telephone number of the individual having the most knowledge of specific requirements and capabilities of requested equipment. If requested equipment is required by a Technical Manual (TM) attach a copy of the page from the TM listing this equipment. If the equipment requested is for training, the following information is required as part of your justification.

- 1. Equipment to student ratio.
- 2. Number and types of classes taught per year.
- 3. Number of students per class.
- 4. Interrelationship of the equipment.
- 5. A Program of Instruction (POI) which lists required equipment should be attached to DA Form 4610-R. It must include the student-to-equipment ratio and the size, frequency, and length of classes.
  - 6. Basis of Issue Plan (BOIP) involved, if any.

Remember: There is no medical representation on the G-3 Equipment Review and Validation Board, therefore, the justification should be clear and succinctly written; able to stand on it's own to the lay reader. If members of the board cannot understand what the item is and why we need it, most likely it will be returned for additional clarification/justification. Each part of the DA Form 4610-R must be completed. "NA" will be used when the part is not applicable.

#### How to Prepare A DA Form 4840-R, Request For Type Classification Exception/LIN Assignment For Commercial Equipment

Prepare DA Form 4840-R requesting exemption from type classification or LIN assignment for commercial nonstandard equipment with a unit cost \$250,000 and over as follows:

#### I. Part 1. Heading

- 1. Date: Indicate the date of document preparation.
- 2. TDA/JTA Number: Enter complete TDA number, to include command code (e.g. MCW2LAA). MC represents MEDCOM and should go before the UIC in this block.
- 3. Name and Address of Requesting Activity. Enter complete name and mailing address of requesting TDA activity. Also enter CCNUM of TDA and TDA paragraph number in which the item will be documented.
- II. Section I, Request For Exemption From Type Classification
- 4. Proposed Nomenclature. Enter proposed nomenclature of requested item and quantity requested.
- 5. Equipment Function and Required Characteristics. Enter the function the equipment will be required to perform and characteristics required. (See AR 71-32, Chapter 6, for additional requirements.
- 6. LIN Considered And Not Acceptable For The Following Reasons. Enter LIN considered not acceptable for the following reasons for non-acceptance. Conclude with the statement "There is no acceptable standard item in the supply system."
  - 7. Date Item is Required. Date item is required to be on hand.

#### III Part II - Request For LIN

- 8. Full Name of Manufacturer. Enter the full name of manufacturer (Not vendor/distributor
- 9. FSCM. Enter Federal Supply Code for Manufacturer or Commercial and Government Entity (CAGE) code.
- 10. Address of Manufacturer. Enter the full address of the manufacturer (not the address of the vendor/distributor).
- 11. Model Number Assigned by Manufacturer. Enter model number assigned by the manufacturer. <u>Do not include the serial number</u>.
- 12. Part Number Assigned by Manufacturer. Enter part number assigned by manufacturer. Note: DA Form 4840-R cannot be processed for exemption from type classification without a model number or a part number. At least one of these is required.
  - 13. NSN: Enter national stock number, if known.
  - 14. Unit Cost. Enter unit cost, not total cost, if you are requesting more than one.
  - 15. Info Attached. Place an "X" in the appropriate box(s). One of these must be attached.
  - 16. AMC Exemption From Type Classification Received. For LIN assignment: Not applicable.

- 17. Remarks. Enter complete justification for requested item and the procurement appropriation in which this requirement will be included. For TMDE, include TMDE registration number per AR 750-43.
- 18. Person Most Knowledgeable With The Technical Requirements For the Item. Enter the name of the individual having knowledge of specific requirements and capabilities of requested equipment. Include address, phone number and DSN number of individual.
  - 19. Name and Tile of Individual Responsible For Item
  - 20. Signature. Signature of responsible individual whose name appears in block 19.

EQUIPMENT CHANGES IN MTOE/TDA  For use of this form, see AR 71-32: the proponent agency is ODCSOPS																	
1. TITLE OF THE FUNCTIONAL AREA										2. UIC	2. UIC						
DENCOM											W2DNAA						
3. UNIT DESIGNATION 4. MTOE/TDA NUMBER										5. CCI							
BROOKE ARMY MEDICAL CENTER, FORT SAM HOUSTON, TX 78248 MCW2DNAA										010	)/						
	PART I - EQUIPMENT																
SECTION A – ITEMS TO BE ADDED AND/OR DELETED																	
ITEM	PARA	LIN	ERC	SB 70	00-20	Nomenclature	cost			QUANTITY DELETED NEW PARA QTY		ARA QTY	NEW RECAP QTY		Qty On Hand		
NO	17000		Litto	CHA	PTER	(basic noun)		REQ	AUTH	REC		H REQ	AUTH	REQ	AUTH	Not Auth	t Auth
1.	811	D95343	С		2	Dent Equip Set, Dent Spt	11,762	2	2	0	0	2	2	2	2		0
	SECTION B – ITEMS TO BE DELETED FROM OTHER MTOE/TDA																
ITEM	PARA	LIN	ERC		00-20	Nomenclature	COST										
NO	TAKA	LIIV	LIKO	CHA	PTER	(basic noun)	0001										
						N/A											
					PART	II - PERSONNEL - NUMBER (	OF POSITIO	NS TO BE	ADDED	(A) AN	ID/OR DE	LETED (D)					
ITEM	PARA LINE No. Positions DESCRIPTION GR MOS ASI/LIC BR ID				AMSC		NEW R										
NO.	DESCRIPTION									R	EQ	AUTH					
	N/A																

DA FORM 4610-R, SEP 96 USAPPC V2.00

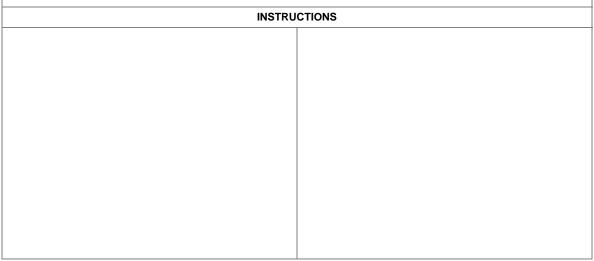
EDITION OF DA FORM 4610-R, JAN 80 IS OBSOLETE.

Figure 2-1

#### **PART III - JUSTIFICATION**

The US Army Dental Command has the need to add a limited number of TOE equipment sets for training. Three set have been added on an earlier submission. This one was returned for review. The sets will be included in the TDA of Brooke Army Medical Center. The equipment will be maintained at Fort Sam Houston, Texas for the purpose of (1) equipment training and familiarization by Dental Corps officers attending the AMEDD Basic Officer Leadership Course (BOLC) and the AMEDD Advanced Course, (2) backup to contingency missions at mobilization/demobilization at CONUS based Power Projection Platforms not co-located with fixed Dental Command dental treatment facilities, (3) dental humanitarian assistance missions for which the DENCOM is tasked, outside of FORSCOM TOE chain of support. Future requests for exceptions to allow additional procurement of equipment sets may follow, as doctrinal guidance for Homeland Defense may involve the US Army Dental Command. In the current OPTEMPO many of our dentists are being pulled from our fixed facilities with no familiarization with TOE equipment. The TOE dental sets are completely different than what they work with in a fixed environment. This familiarization and training will allow the individual to perform at a high level in the minimum amount of time due to his knowledge and working order of his equipment.

POC is COL John Jones Chief of Staff US Army Dental Command 210-221-8241



PAGE 2, DA FORM 4610-R, SEP 96

USAPPC V2.00

Figure 2-2

#### CHAPTER 1. VACCINES AND TEMPERATURE-SENSITIVE MEDICAL PRODUCTS

# 1-1. THE U.S. ARMY MEDICAL MATERIEL AGENCY (USAMMA) DISTRIBUTION OPERATIONS CENTER (MCMR-MMO-SO)

- a. The *DOD Directive 6205.3* sets DOD policy for the use of vaccines for biological defense and designates the US Army as the DOD Executive Agent for the DOD Immunization Program for Biological Warfare Defense.
- b. In 1998 the USAMMA was tasked with coordinating the distribution of anthrax vaccine from the manufacturer to DOD medical facilities. To accomplish this mission and in support of the Anthrax Vaccine Immunization Program (AVIP), USAMMA established the Distribution Operations Center (DOC) to work closely with tri-Service field and fixed medical activities. It is structured within the USAMMA's Force Sustainment Directorate and an integral part of the DoD Military Vaccine (MILVAX) Agency. (Reference Department of the Army (DA) Supply Bulletin (SB) SB 8-75-S1, paragraph 3-8, dated 20 January 2007.)
- c. Subsequently, in 2002 the DOC was also tasked with coordinating the DoD distribution of smallpox vaccine from the Centers for Disease Control and Prevention (CDC) to DOD medical facilities for the Smallpox Vaccine Program (SVP).
- d. The USAMMA DOC also supports other DoD and Federal agencies when shipping Temperature-Sensitive Medical Products (TSMPs) to ensure the cold chain is maintained. (Reference DA *SB 8-75-11*, dated 30 November 2006, paragraph 9-8, b.) It also supports critical medical products to include Investigational New Drugs (INDs) and Foreign Military Sales (FMS).
- e. In addition to it's DoD areas of responsibility, the DOC is also the Service Inventory Control Point for the Army's Influenza Virus (Flu) Vaccine.
- f. To minimize loss of product and expedite delivery of vaccine to requesting sites, the DOC performs redistribution of these vaccines when required. It also maintains and provides supporting TSMP equipment to sites when needed.
- g. The USAMMA's DOC creates, publishes, and disseminates Medical Materiel Quality Control (MMQC) messages to DOD medical facilities providing advanced notification of pending expiration dates of anthrax vaccine and smallpox vaccine. The DOC also creates, publishes, and disseminates MMQC messages to DOD medical facilities providing program, policy, and guidance for anthrax vaccine and smallpox vaccine, and Medical Materiel Information (MMI) messages to Army facilities reflecting program policy and guidance related to influenza vaccine. (Reference DA *SB 8-75-S1*, dated 20 January 2007, paragraph 4-6, and *SB 8-75-11*, dated 30 November 2006, paragraph 4-2.)

#### h. Sources of Information

(1) Direct any questions regarding these vaccines and TSMPs to the USAMMA DOC at the following address and/or website:

**USAMMA** 

ATTN: MCMR-MMO-SO 1423 Sultan DR

Fort Detrick MD 21702-5001

DSN 343, Commercial 301-619-7235, 4198, 4318

Fax: 301-619-4468

Email: <u>USAMMADOC@amedd.army.mil</u>

(2) The USAMMA DOC World Wide Web (WWW) site: available on the USAMMA Homepage at <a href="http://www.usamma.army.mil">http://www.usamma.army.mil</a>, select "Vaccines and Temperature Sensitive Products" and follow appropriate prompts; or

(3) Go directly to the USAMMA DOC website: <a href="http://www.usamma.army.mil/vaccines/vaccines.cfm">http://www.usamma.army.mil/vaccines/vaccines.cfm</a>

#### **CHAPTER 2. MEDICAL MATERIEL INSTRUCTIONS**

# 2-1. SUBMITTING MEDICAL/DENTAL PRODUCT QUALITY DEFICIENCY REPORTS (M/DPQDR) – [FORMERLY MEDICAL MATERIEL COMPLAINTS (SF 380S)]

- a. All medical materiel complaints, regardless of procurement source, should be submitted on a Medical or Dental Product Quality Deficiency Report (M/DPQDR). A M/DPQDR should be submitted to report materiel or equipment that has been determined to be harmful and/or defective that may result in death, injury, or illness. The M/DPQDRs are categorized into two types:
- Category I: Materiel that has been determined by use or testing to be harmful or defective to the extent that its use has or may cause death, injury, or serious illness.
- Category II: Drugs, devices, supplies, or equipment that is suspected of being harmful, defective, deteriorated, or unsatisfactory because of malfunction or design, which are attributable to faulty materiel, workmanship and/or quality inspection, or performance or are otherwise unsuitable for use.
- b. An M/DPQDR is the customer's way of alerting the system that there is a quality deficiency with a medical or dental product. Deficiencies should be submitted on standard and nonstandard items. It is also the vehicle for submitting Safe Medical Device (SMD) incidents. Examples of discrepancies which should be reported on the M/DPQDR are:
  - · Wrong or deficient labeling
  - Foreign or particulate matter in liquids and solids
  - Imperfectly manufactured items which are off-color, off-taste, and off-odor
  - Suspected sub-potency or super-potency
  - Defective devices
  - Pinholes in tubing
  - Faulty calibrations
  - Systemic equipment failures
  - Poor quality products
- c. The submitter will receive a copy of the e-mail that has been sent to DSCP, the Defense Medical Standardization Board (DMSB) and the Services' Medical Logistic Offices at Ft Detrick. Once the form is received, DSCP will assign a Report Control Number (RCN) in the Product Data Reporting and Evaluation Program (PDREP), and respond back to you normally within two days. For more information about the PDREP program go to the following website:

http://www.nslcptsmh.navsea.navy.mil/pdrep/pdrep.htm

- d. Report the circumstances of Category I (Type I complaints) immediately to DSCP, through the M/DPQDR, or by telephone.
- (1) During normal duty hours (0700 1700 hours Eastern Time), call the DSCP Emergency Supply Operations Center (ESOC) at DSN 444-2111/2112, or commercial 215 737-2112. A telefax may also be sent to: Commercial 215 737-2081/7109 or DSN 444-2081/7109.

- (2) After duty hours, the numbers called above will automatically transfer to the Staff Duty Officer. If the transfer does not occur or the call is not answered, call the following numbers: DSN 444-2341 or commercial 215 737-2341.
- e. The *21 CFR* prescribes reporting certain materiel/equipment conditions to the FDA under the Safe Medical Devices Act (SMDA). Logistics personnel will coordinate and provide a copy of the Complaint Form to the Risk Manager as part of the Risk Management Program. The Risk Manager is required under Joint Commission on Accreditation of Healthcare Organization (JCAHO) to review the SMDA information on the Complaint Form and assess the potential risk.

\*\*\*A sample of the M/DPQDR is shown at Appendix A. \*\*\*

# 2-2. DEPARTMENT OF DEFENSE MEDICAL MATERIEL QUALITY CONTROL (DOD-MMQC) MESSAGES AND DEPARTMENT OF THE ARMY MEDICAL MATERIEL INFORMATION (MMI) MESSAGES

- a. The DoD-MMQC messages is a Tri-Service centralized reporting system developed to maintain a readiness posture by providing our MTOE activities, ships, and other deployed field units the same quality assurance (QA) information afforded fixed/TDA facilities. The DoD-MMQC process is an Integrated Medical Logistics Group initiative, designed to simultaneously disseminate QC information and rapidly notify hospitals, clinics, and medical units aboard ships or on foreign soil of potentially hazardous medical materiel. These messages contain urgent QA data emanating from pharmaceutical and/or medical device and equipment manufacturers regarding their products.
- b. Once received at the Defense Supply Center Philadelphia (DSCP), research is conducted by DSCP and USAMMA's Distribution Operations Center (DOC) (MCMR-MMO-SO) to equate the product with National Stock Numbers (NSNs). The USAMMA's DOC then incorporates information into the DoD-MMQC message format that contains all Service-specific requirements, Point of Contact (POC), reason for message, disposition instructions, and any other product related information. The program's primary purpose is to aid the Service-specific logisticians, supply managers, pharmacists, clinicians, medical maintenance personnel, in assuring that the proper use, handling, and return of recalled product is accomplished to protect patient safety.

#### c. The recalls are classified as follows:

- (1) Class I: A situation in which there is a reasonable probability that use of, or exposure to, a dangerous product will cause serious adverse health consequences or death.
- (2) Class II: A situation in which the use of, or exposure to, a dangerous product may cause adverse health consequences.
- (3) Class III: A situation in which the use of, or exposure to, a dangerous product is not likely to cause adverse health consequences.
- d. The DOC also disseminates Army Medical Materiel Information (MMI) messages that contain information specific to the Army only.

- e. These messages are available via two media (Reference Department of the Army SB dated 20 January 2007, *SB 8-75-S1*, paragraph 4-6 and SB dated 30 November 2006, *SB 8-75-11*, paragraph 4-2):
- (1) The World Wide Web (WWW) (available on the USAMMA Homepage at http://www.usamma.army.mil. Select "DoD-MMQC Messages" and follow appropriate prompts.
- (2) Electronic Mail. Register to receive DoD-MMQC and MMI messages via e-mail by subscribing on USAMMA's website (address above). Select "DoD-MMQC Messages" the "Subscribe to MMQC Messages Here" and provide all required information.
  - f. These messages are also disseminated via:
- (1) File-transfer protocol (FTP) to USAMMCE (Germany) and 16<sup>th</sup> MLB (Korea)
  - (2) Joint Medical Asset Repository (JMAR)
  - (3) Defense Medical Logistics Supply System (DMLSS)

#### 2-3. SAFE MEDICAL DEVICE ACT (SMDA) OF 1990

- a. References:
  - (1) AR 40-61, Chapter 4, Section V, Para 4-13 and 4-14
  - (2) FDA Medical Device Report (MDR) Regulation (Website: www.fda.gov)
  - (3) Medical/Dental Product Quality Deficiency Report (M/DPQDR)
- b. Effective 28 November 1991, all Medical Treatment Facilities (MTFs) are required to report device-related deaths, serious injuries and reportable malfunctions.
- c. The M/DPQDR and the MedWatch 3500A Mandatory Reporting Form, will continue to be used in submitting the incidents, and is not limited to devices, and includes equipment as well as pharmaceuticals. All Activities should continue to submit M/DPQDRs, IAW AR 40-61, dated 28 Jan 2006, Chapter 4, Section V, Para 4-13 and 4-14.
- d. M/DPQDR reports are not defined as Type I, Type II or Type III complaints [as previously identified with Medical Materiel Complaints (SF 380's)]. Categories of the M/DPQDR are as a Category 1 or 2:
- A category 1 complaint is an item or event that could cause serious injury or illness or loss of life. Category 1 can only be submitted with the approval of a medical officer.
  - All others are Category 2.
- e. User-facilities such as hospitals and nursing homes are legally required to report suspected medical device-related deaths to both the Food and Drug Administration (FDA) and the manufacturer, if known, and serious injuries to the manufacturer or to FDA, if the manufacturer is unknown. These reports must be made on the MedWatch 3500A Mandatory Reporting Form.

- f. The statutory authority for the MDR regulation is section 519(a) of the Federal Food Drug & Cosmetic (FFD&C) Act as amended by the SMDA of 1990. The SMDA requires user facilities to report:
  - (1) device-related deaths to the FDA and the device manufacturer;
- (2) device-related serious injuries to the manufacturer, or to FDA if the manufacturer is not known; and
- (3) submit to FDA on an annual basis a summary of all reports submitted during that period
- g. The SMDA requires FDA to issue regulations requiring distributors to report device-related deaths, serious injuries and reportable malfunctions. In addition, the SMDA requires distributors and manufacturers to certify to FDA the number of MDR reports filed or that no reports have been filed. All manufacturers of finished medical devices and components which are ready for use, including foreign manufacturer's are now subject to the requirements of the MDR regulation, despite registration status.

## 2-4. SUBMITTING SUPPLY DISCREPANCY REPORTS (WebSDR) – [FORMERLY REPORTS OF DISCREPANCY (SF 364)]

- a. All Supply Discrepancy Reports should be done electronically under the Department of Defense's Supply Discrepancy Reporting (SDR) system created by the Defense Logistics Agency (DLA). The Defense Automatic Addressing Service Center (DAASC) is responsible for the development and support of this project.
- b. The goal of WebSDR is to move SDRs into an integrated transactional environment thereby providing an effective means to report and measure discrepancy related data and pipeline performance and to help achieve near real time SDR reporting, enable Perfect Order Fulfillment computations, facilitate interoperability internal and external to DoD, and maximize the economy, efficiency, effectiveness of the reporting process.
  - c. To submit a SDR on-line, go to: https://www.daas.dla.mil/websdr
- d. You must register, providing all information required; once complete, submit and you will be provided a password. Once received, then comply with instructions outlined. For more information on this web site and the WebSDR Application, choose "Contact Us" (top right hand corner) on web page.

#### 2-5. POINT OF CONTACT

Questions regarding these medical materiel instructions may be directed to:

USAMMA
ATTN: MCMR-MMO-SO
1423 Sultan DR
Fort Detrick MD 21702-5001
DSN 343-4300/3242 or Commercial 301-619-4300/3242

#### APPENDIX A. SAMPLE M/DPQDR

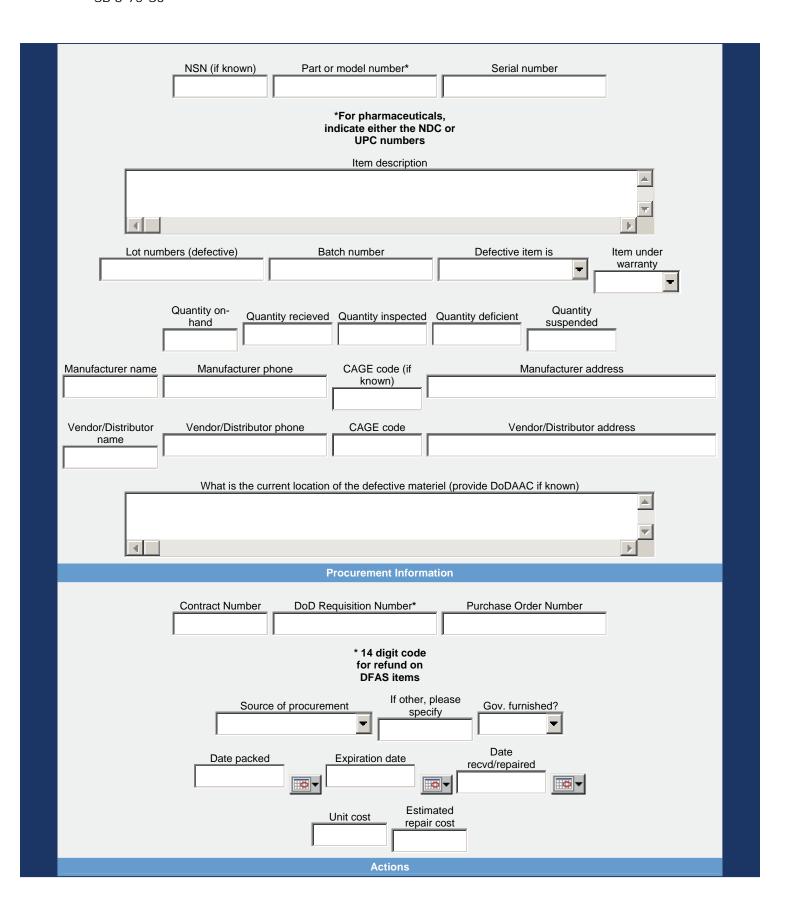


#### The Warfighter's Medical Logistics Portal



Med/Surg Equipment Readiness Site Log In Pharm **Medical/Dental Product Quality Deficiency Report** Complete the following data fields that are applicable to your Medical/Dental Product Quality Deficiency Report (M/DPQDR). The M/DPQDR replaces the Standard Form 380 (SF380). The submitter must provide an accurate email address and will automatically receive a copy of data submitted. When finished, click on the Submit button at the bottom. For further instructions about how this form should be completed, please click here. Date deficiency Assigned found or Document Number event Φ. occurred **Complaint Information** I Product or event that could Category: cause serious injury or death Ō II All others Cause of Complaint - Explanation of unsatisfactory condition, deficiency, or description of reaction Approximate amount of time in use before failure(days) Total Total **Patients** patients without reactions involved reaction Note: Complete the following items for DoD category I complaints only Reactions requiring Length of Severe or hospitalization hospital stay unusual (days) reactions

**Product Information** 



Has the manufacturer or distributor been notified?
Do you seek credit or replacement?  Credit N/A
MedWatch Report
Was the MedWatch Report submitted  Yes No N/A  If Mandatory 3500A Form http://www.fda.gov/medwatch/safety/3500a.pdf  Voluntary 3500 Form https://www.accessdata.fda.gov/scripts/medwatch  If no, do you want DSCP to submit a Voluntary MedWatch Report for you? We will provide  Yes No N/A
you a copy of what is reported.
From
Activity name DoDAAC Activity address
Submitter's name DSN phone Comm. phone Fax Email
Supply Officer's DSN phone Comm. phone Fax Email
PoC for additional DSN phone Comm. phone Fax Email

Authorizing Medical Officer for Category I complaints DSN phon	e Comm. phone	Fax	Email
Any other comments	or questions relating to this complaint	<u> </u>	
		_	
	Submit Query  Start over		

# **GLOSSARY**

#### **2007 GLOSSARY FOR SB 8-75-S3**

### Abbreviation/Acronym Definition AMEDD -----Army Medical Department AVIP-----Anthrax Vaccine Immunization Program CFR ----- Code of Federal Regulations DA ----- Department of the Army DAASC----- Defense Automatic Addressing Service Center DOC ----- Distribution Operations Center DLA ------ Defense Logistics Agency DMLSS------ Defense Medical Logistics Supply System DOD ----- Department of Defense DOD-MMQC ----- Department Of Defense Medical Materiel Quality Control DMSB ----- Defense Medical Standardization Board DSCP ----- Defense Supply Center Philadelphia DSN------ Defense Switched Network ESOC ------ Emergency Supply Operations Center FDA ----- Food and Drug Administration FFD&C ------ Federal Food Drug & Cosmetic FMS------Foreign Military Sales FTP ------ File Transfer Protocol IND------ Investigational New Drug JCAHO ----- Joint Commission on Accreditation of Healthcare Organization JMAR ----- Joint Medical Asset Repository MILVAX Agency----- Military Vaccine Agency MMI ----- Medical Materiel Information MMQC ----- Medical Materiel Quality Control M/DPQDR----- Medical or Dental Product Quality Deficiency Report NSN------ National Stock Number PDREP ----- Product Data Reporting and Evaluation Program POC ------Point of Contact PQDR ------ Product Quality Deficiency Report QDR ----- Quality Deficiency Report RCN------ Report Control Number SB------Supply Bulletin SF------Standard Form SDR------ Supply Discrepancy Reporting SMD ------ Safe Medical Device

SMDA ------ Safe Medical Devices Act SVP------Smallpox Vaccine Program

#### Continued - 2007 GLOSSARY FOR SB 8-75-S3

## 

### 2006 INDEX - SB 8-75-S3

SUBJECT	SB 8-75-	PAGE
Department Of Defense Medical Materiel Quality Control (DOD-MMQC) Messages And Department Of The Army Medical Materiel Information (MMI) Messages	<b>S</b> 3	2-2
Errata Sheet With Attachments for SB 8-75-S1	S3	ES-1
Glossary For SB 8-75-S3	S3	GL-1
Point Of Contact	<b>S</b> 3	2-4
Safe Medical Device Act (SMDA) Of 1990 Sample Form for M/DPQDR Submitting Medical/Deptal Product Quality Deficiency Paperts (M/DPQDR)	S3 S3	2-3 A-1
Submitting Medical/Dental Product Quality Deficiency Reports (M/DPQDR)  – [Formerly Medical Materiel Complaints (SF 380s)]	S3	2-4
Submitting Supply Discrepancy Reports (WebSDR) – [Formerly Reports Of Discrepancy (SF 364)]	S3	2-1
The U.S. Army Medical Materiel Agency (USAMMA) Distribution Operations Center (MCMR-MMO-SO)	S3	1-1

By Order of the Secretary of the Army:

PETER J. SCHOOMAKER General, United States Army Chief of Staff

Official:

JOYCE E. MORROW Administrative Assistant to the

Secretary of the Army

#### Distribution:

To be distributed in accordance with initial distribution number (IDN) 340016, requirements for the SB 8-75 Series.

PIN: 063917-000